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EXAMINER

PAPPU, SITA S

ART UNIT PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,485

Applicant(s)

LYLES, MARK B.

Examiner

Sita Pappu

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Claims 1-33 are pending in the instant application. This paper contains an examination of the claims 1-33 on their merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

The nucleic acids comprising the sunscreen formulation are on sale by Sigma Chemical Company (see Sigma Catalog, Catalog # D7290). The herring sperm DNA that comprises the sunscreen formulation of the instant invention is available from Sigma Chemical Company. The DNA sold by Sigma Chemical Company comigrates with marker fragments that are between 587-831 base pair long and thus encompasses the DNA of claim 3, which is at least about 100 base pairs.

Since the claim is directed to a composition, the intended use of the claimed composition is given patentable weight when making a determination of patentability under 35 U.S.C. 102 only when it serves to define a structural requirement. In composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Furthermore, the preamble is generally nonlimiting if it

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merely recites an inherent property. See MPEP 2111.02. In the instant case, the prior art structure has all the features required to perform the intended use recited in the claims. Furthermore, as there are no claimed distinguishing features between the claimed nucleic acids and those sold by Sigma company, the intended use as a sunscreen is an inherent feature of the product. The claiming of a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2112.

Claims 1-4 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

The nucleic acids comprising the sunscreen formulation are in use in a method for Southern hybridization protocol of Research Division Laboratory Manual by David Bowtell of PMCI (1998; Peter Mac Laboratory Manual, University of Melbourne, Australia). The concentration at which the formulation is used in the protocol taught by the manual is 100 µg/ml.

Since the claim is directed to a composition, the intended use of the claimed composition is given patentable weight when making a determination of patentability under 35 U.S.C. 102 only when it serves to define a structural requirement. In composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Furthermore, the preamble is generally nonlimiting if it

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merely recites an inherent property. See MPEP 2111.02. In the instant case, the prior art structure has all the features required to perform the intended use recited in the claims. Furthermore, as there are no claimed distinguishing features between the claimed nucleic acids and those used in the procedure of the Peter Mac Lab Manual, the intended use as a sunscreen is an inherent feature of the product. The claiming of a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2112.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Li, Y-X.

(US patent No. 6,117,846).

Claims 1-4:

U. S. Patent 6,117,846 teaches the use of nucleic acids as a sunscreen, wherein the nucleic acids are of the size between 100-5000 base pairs (see claim 9, Li). The inventor, Li describes (see column 3, bottom paragraph) that "the nucleic acid of the invention is used to selectively absorb, and thereby remove, nucleic acid-damaging ultraviolet radiation from artificial sources or from sunlight", which is what a sunscreen formulation does. Further, Li discloses, in the 'Background of the Invention' section

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(bridging paragraph of columns 2 and 3; column 3, lines 4-46) that his invention deals with sunscreen formulations, and that his invention overcomes problems presented by physical and chemical sunscreens (column 4, lines 10-12). Claim 3 of the instant case recites the use of the nucleic acids at a concentration of 'at least about 0.01% (w/v). In Example 2 (column 7), Li discloses the formulation of a DNA-containing lotion wherein the DNA concentration was 0.1 % (w/v), which encompasses the range of at least about 0.01 % recited in claim 3 of the instant case. Thus, Li anticipated the sunscreen formulation of claims 1-4 of the instant case.

Claims 5-17:

U.S. Patent 6,117, 846 teaches the use of nucleic acid containing formulations for absorbing the ultraviolet radiation, by interposing a nucleic acid-containing barrier between a source of UV radiation and a living organism (see abstract) and exemplified the invention in the form of a cream applied to the surface of a target (column 3, lines 58-62). In particular, U.S. Patent 6,117, 846 teaches that a nucleic acid-containing lotion or cream is applied to a surface such as skin to shield an animal from exposure to damaging ultraviolet radiation (column 4, lines 7-9). As described above for claims 1-4, the nucleic acid of the invention is a DNA of 100-5000 base pairs used to absorb UV radiation. Column 4, lines 23-43, teach that the invention of Li results in less ultraviolet radiation being absorbed by the treated living organism. Further, Li teaches that his invention relates to the use of nucleic acids as a filter for living organisms such as

plants, animals including humans (column 1, lines 7-12). Thus, Li anticipated the method of claims 5-17.

Claims 18-26:

U.S. Patent 6,117,846 teaches the use of a method to reduce the occurrence of skin cancer wherein the method comprises applying a sunscreen formulation comprising nucleic acids to the skin of a living organism. Column 10, lines 45-56 teach that one of the principal ways ultraviolet radiation causes cancer is through the formation of ultraviolet light-induced pyrimidine dimers which can lead to permanent mutations in the genetic code and that this form of mutagenesis is widely believed to be the major route through which sunlight induces both melanoma and malignant non-melanoma skin cancers. Further, Li teaches that his invention in the form of a lotion or cream is applied to the skin of an animal to shield it from exposure to damaging ultraviolet radiation (column 4, lines 7-9), and that the use of his nucleic acid filter as a sunlight filter provides selective absorption of the specific UV spectra that cause cancer-inducing genetic damage, while allowing other, beneficial wavelengths of sunlight to shine upon epidermal cells (column 4, lines 12-21). Further, Li teaches that his invention relates to the use of nucleic acids as a filter for living organisms such as plants, animals including humans (column 1, lines 7-12). In particular, Li teaches and claims a method for protecting an animal from ultraviolet radiation-induced genetic damage relative to an unprotected control (see Li, U.S. Patent 6,117,846, column 15, claim 6), and protecting

an animal from UV-induced genetic damage encompasses "reducing the occurrence of cancer" because skin cancer is UV-induced genetic damage, as taught by Li (column 10, lines 45-56). Thus, Li anticipated the method of claims 18-26.

Claims 27-33:

U.S. Patent 6,117,846 teaches the use of a method to reduce the sunburning of a living organism wherein the method comprises applying a sunscreen formulation comprising nucleic acids to the skin of a living organism. Li teaches that the nucleic acids of his invention in the form of a lotion or cream is applied to the skin of an animal to shield it from exposure to damaging ultraviolet radiation (column 4, lines 7-9), and that the use of his nucleic acid filter as a sunlight filter provides selective absorption of the specific UV spectra that cause cancer-inducing genetic damage, while allowing other, beneficial wavelengths of sunlight to shine upon epidermal cells (column 4, lines 12-21). Further, Li teaches that his invention relates to the use of nucleic acids as a filter for living organisms such as plants, animals including humans (column 1, lines 7-12). Thus, Li anticipated the method of claims 27-33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ananthaswamy et al. (1999; Journal of Investigative Dermatology, vol. 112, no. 5, pp 763-768) and Gilchrest et al. (U.S. Patent No. 6,147,056).

Ananthaswamy et al. (1999) teach that p53 mutations can be detected in ultraviolet B-irradiated mouse skin months before the appearance of skin tumors and that applying sunscreens led to a reduction of ultraviolet-induced p53 mutations and protection against skin cancer. Ananthaswamy et al. (1999) teach that less than 5% of the mice treated with sunscreens plus ultraviolet light showed evidence of p53 mutations. Thus, Ananthaswamy et al. (1999) demonstrated the reduction of p53 mutations as a measure of quantification of the protection against skin cancer (see abstract).

Ananthaswamy et al. (1999) do not teach the protective effect using sunscreens comprising nucleic acids.

Gilchrest et al. teach the use of nucleic acids, of 2-200 bases in length (column 3, lines 60-63), as a topical application (column 2, lines 25-26), in a method of reducing

skin cancer in a mammal, wherein the skin cancer is a result of exposure to the sun (column 2, lines 10-14).

Gilchrest et al. do not teach various measures of quantification of their method of reducing skin cancer.

Therefore, it would have been obvious to one of ordinary skill in the art to substitute the sunscreen of Ananthaswamy et al. (1999) with the sunscreen of Gilchrest et al. and quantify the protective effect of the nucleic acid-containing sunscreen in reducing the occurrence of skin cancer. The motivation to do so, with an expectation of success, was taught by Ananthaswamy et al. (1999) who successfully demonstrated that sunscreens are effective in reducing the occurrence of skin cancer and that their method can be used in quantifying the protection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746 7442 for regular communications and (703) 746 7442 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305 2982.

S. Pappu
January 25, 2002

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER